BIOLOGIC PRODUCT DEVIATION REPORTING (BPDR) – COMPANY POSITION

In line with the BLA license approval, 21 CFR 600.14 regulations, and previous communication that Biologic Product Deviation Reports (BPDRs) were not required for the Pfizer-BioNTech COVID-19 Vaccine authorized under the EUA the following approach will be taken:

- A BPDR is required and would be issued for COVID-19 Vaccine lots manufactured and released in accordance with the approved BLA and certified by CBER (lot has received an approved CBER lot release certificate).

- A BPDR is not required and will not be issued for COVID-19 Vaccine lots manufactured and released in accordance with the EUA only. As noted by Dr. Ramachandra Naik, FDA, in email correspondence to Donna Boyce on December, 17, 2020, FDA indicated that Biologic Product Deviation Reports (BPDRs) are not required to be submitted for the Pfizer-BioNTech COVID-19 Vaccine authorized under EUA, as they are for licensed products under 21 CFR 600.14.

- If a COVID-19 Vaccine lot manufactured and released in accordance with the EUA is included in the scope of a deviation requiring a BPDR for a COVID-19 Vaccine lot manufactured and released in accordance with the approved BLA, then the EUA lot number will be included in the Additional Comments section of the BPDR to ensure transparency.